

Remarks

Claims 1-13, 16-21, and 24-26 are pending in the subject application. Applicants gratefully acknowledge the Examiner's withdrawal of the rejections under 35 USC §112, first paragraph, and 35 USC §102(b). By this Amendment, Applicants have cancelled claim 9, amended claims 10-13, 16, 17, 20, 21, and 24-26 and added new claims 27-36. Support for the new claims and amendments can be found throughout the subject specification and in the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 1-8, 10-13, 16-21, and 24-36 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

Submitted herewith is a Request for Continued Examination (RCE) under 37 CFR §1.114 for the subject application.

Claim 26 is objected to by the Examiner as being of improper dependent form for failing to further limit claim 1. Applicant respectfully submits that claim 26 specifies that the particle comprises "chitosan", whereas claim 1 is open to chitosan or a "chitosan derivative." Thus, Applicant respectfully asserts claim 26 does further limit claim 1. Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

Claims 1-8, 10-13, 16-21, and 24-26 have been rejected under 35 USC §102(e) as anticipated by Ni *et al.* (U.S. Published Patent Application No. 2002/015009). Ni *et al.* is cited as teaching a composition comprising DNA, chitosan and a lipid. Applicant respectfully traverses this ground of rejection.

Applicant respectfully asserts that the Ni *et al.* publication does not teach or suggest Applicant's claimed invention. Specifically, Applicant respectfully asserts that the Ni *et al.* publication does not teach a composition or particle comprising a polynucleotide, a lipid, and chitosan or a chitosan derivative. The Examiner references various paragraphs from throughout the Ni *et al.* publication to try and show that Ni *et al.* teach a composition comprising all three of a polynucleotide, a lipid, and chitosan (or a chitosan derivative). However, Applicant respectfully asserts that Ni *et al.* does not disclose an embodiment wherein all three of a polynucleotide, a lipid, and chitosan (or a chitosan derivative) are disclosed within a single embodiment. At paragraphs

0410-0411 of the Ni *et al.* publication, the Examiner asserts that Ni *et al.* teach a compound comprising a nucleic acid and a lipid (“encapsulation in liposomes”). This section of Ni *et al.* does not teach or suggest a compound comprising chitosan and, therefore, does not teach or suggest all the elements of Applicant’s claimed invention. In paragraph 1032 of the Ni *et al.* publication, the Examiner asserts that Ni *et al.* teaches a formulation comprising nucleic acid and chitosan. This section of the Ni *et al.* publication does not teach or suggest a composition comprising a lipid and, therefore, again does not teach or suggest all three elements of Applicant’s claimed invention. The Examiner then references paragraph 1034 of the Ni *et al.* publication as teaching a composition comprising “release rate modification agents” which the Examiner asserts includes “pore-forming agents such as fatty acids (lipids).” However, Applicant respectfully asserts that this section of the Ni *et al.* publication does not teach or suggest the combination of all three of the elements: a polynucleotide, a lipid, and chitosan (or a chitosan derivative) in a particulate form. Thus, the Ni *et al.* publication does not teach each and every element of independent claims 1, 10, 17, and 21, and claims dependent therefrom.

In regard to claims 2, 6, and 11, the Examiner asserts that it is well-established in the art that the delivery of nucleic acids in particles comprising chitosan or liposomes is in the nanoscale. However, a particle of chitosan, *etc.*, does not necessarily have to be in the nanoscale. Moreover, Applicant respectfully submits that there is no explicit teaching or suggestion in the Ni *et al.* publication of a particle comprising a polynucleotide, a lipid, and chitosan (or a chitosan derivative) that is in the nanoscale. Thus, the Ni *et al.* publication does not teach or suggest each and every element of claims 2, 6, and 11.

In regard to claims 3, 4, 7, 8, 12, 13, and 17-20, the Examiner asserts that the Ni *et al.* publication teaches use of an agent to increase cytokine production (paragraph 0666) and teaches the use of interferon gamma (paragraph 1081). Applicant respectfully notes that the claims of the subject application recite that the polynucleotide of the claimed particle encodes a cytokine or interferon gamma. The Ni *et al.* publication does not teach that their therapeutic agent comprises a polynucleotide that encodes a cytokine or interferon-gamma. Paragraph 0666 of the Ni *et al.* publication discloses that “the polynucleotides ... of the present invention may be useful as an agent to increase cytokine production.” (emphasis added); however, there is no mention or teaching that

the polynucleotide encodes a cytokine. Paragraph 1081 of the Ni *et al.* publication discloses that “the Therapeutics of the invention are administered in combination with cytokines” and that the cytokine administered may be “IFN-gamma.” Again, however, there is no mention or teaching that a polynucleotide encoding interferon gamma is administered. Thus, the Ni *et al.* publication does not teach or suggest each and every element of claims 3, 4, 7, 8, 12, 13, and 17-20.

In regard to claim 21, the Examiner asserts that the Ni *et al.* publication teaches creating particles of the invention “through a process of mixing” (paragraph 0418). Claim 21 of the subject application is directed to a process of producing a particle by mixing together a polynucleotide, a lipid, and chitosan or a chitosan derivative. Applicant respectfully asserts the Paragraph 0418 of the Ni *et al.* publication is directed to formulations of a composition, and not to methods of preparing a composition. Moreover, as noted previously herein, the Ni *et al.* publication does not teach or suggest a composition comprising all three of a polynucleotide, a lipid, and chitosan (or a chitosan derivative). Thus, since the Ni *et al.* publication does not teach Applicant’s claimed composition, it cannot teach a method for making that composition. Thus, the Ni *et al.* publication does not teach or suggest each and every element of claim 21 and claims dependent therefrom.

Applicant respectfully maintains that the Ni *et al.* publication does not teach or suggest a composition comprising all three of a polynucleotide, a lipid, and chitosan (or a chitosan derivative) and, therefore, does not teach or suggest methods for making such a composition. As the Examiner is aware, in order to anticipate, a single reference must disclose within the four corners of the document each and every element and limitation contained in the rejected claim. *Scripps Clinic & Research Foundation v. Genentech Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991). The Ni *et al.* publication does not teach each and every element of Applicant’s claimed invention and, thus, does not anticipate the claims. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(e) is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicant’s agreement with or acquiescence in the Examiner’s position.

In view of the foregoing remarks and amendments to the claims, Applicant believes that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicant invites the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachments: Request for Continued Examination  
Petition and Fee for Extension of Time  
Amendment Transmittal Letter